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04-01-04

GAU 1617

POCKET NO.: ADOL-0497/114309.34

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Lawrence I. Kruse, et al.

Confirmation No.: 4357

Application No.: 09/769,450

Group Art Unit: 1617

Filing Date: January 26, 2001

Examiner: Shengjun Wang

For: KAPPA AGONIST COMPOUNDS PHARMACEUTICAL FORMULATIONS
AND METHOD OF PREVENTION AND TREATMENT OF PRURITUS
THEREWITH

EXPRESS MAIL LABEL NO: EV325643503US
DATE OF DEPOSIT: *March 31, 2004*

EV325643503US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☐ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or

before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

☒ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☒ Certification in Accordance with § 1.97(e) is attached;
or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

EXCEPT THAT:

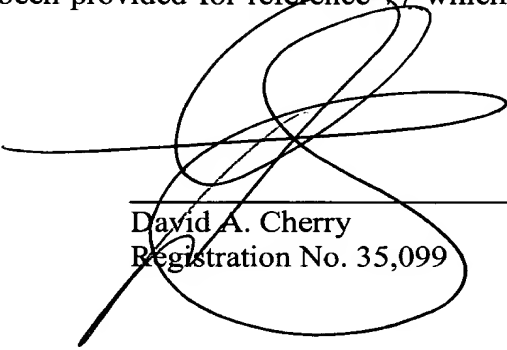
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. _____, filed _____.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Enclosed is a copy of the EPO Communication dated February 26, 2004 (number 73 on Form PTO-1449), which indicates the references considered to be relevant.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ An English language abstract has been provided for reference 77 which is not in the English language.

Date: 3/31/04



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DATE OF DEPOSIT: March 31, 2004

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PEEL OFF STICKER HERE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

CERTIFICATION UNDER 37 CFR § 1.97(e)

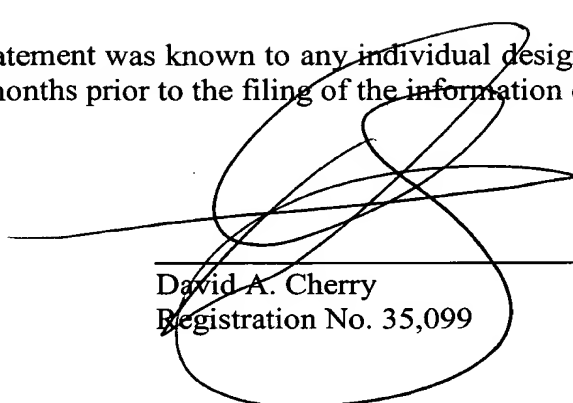
In accordance with 37 CFR § 1.97(e), certification is hereby made that:

- ☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement.
- ☒ No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the

information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Date:

3/31/04



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| Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office | Docket No. ADOL-0497/ 114309.34 | | Application No. 09/769,450 | | |
| | Applicant Lawrence I. Kruse, et al. | | | | |
| | Filing Date January 26, 2001 | | Group 1617 | | |
| | Confirmation No. 4357 | | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | |
| | 73 | Copy of the EPO Communication dated February 26, 2004 (EP 98 935 477.4) | | | |
| | 74 | Scopes, D. I.C., "Selective non-peptide kappa opioid receptor agonists," <i>Exp. Opin. Invest. Drugs</i> , April 1994, 3(4), 369-376 | | | |
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| EXAMINER | | | DATE CONSIDERED | | |



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| Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office | Docket No. ADOL-0497/ 114309.34 | Application No. 09/769,450 |
| | Applicant Lawrence I. Kruse, et al. | |
| | Filing Date January 26, 2001 | Group 1617 |
| | Confirmation No. 4357 | |

U. S. PATENT DOCUMENTS

| Examiner Initial | | Document No. | Date | Name | Class | Subclass |
|------------------|----|--------------|----------|------------------|-------|----------|
| | 75 | 4,466,977 | 08/21/84 | McMillan, et al. | 424 | 274 |
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FOREIGN PATENT DOCUMENTS

| Examiner Initial | | Document No. | Date | Country | Translation | |
|------------------|----|--------------|----------|---------|-------------|----|
| | | | | | YES | NO |
| | 76 | WO 97/32857 | 09/12/97 | PCT | | |
| | 77 | WO 98/23290 | 06/04/98 | PCT | X abstract | |
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